



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Inventor(s): Lehmann, et al.

Serial No. 10/706,701, filed November 12, 2003  
(Ref. No. 21435 US)

For: **TREATMENT OF DISTURBANCES OF IRON DISTRIBUTION**

**INFORMATION DISCLOSURE STATEMENT**

Nutley, New Jersey 07110  
February 11, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, applicants respectfully direct the Examiner's attention to the documents listed on enclosed Form PTO-1449.

Documents B1-B20, and C1-C8 listed on Form PTO-1449 are enclosed. Document B4 is not in the English language and is abstracted in Document C7. Document B19, is not in the English language and is abstracted in Document C8. Copies of documents A1 to A20 are not enclosed as they are U.S. patents.

Copies of documents B21-B26, and C9-C24 are not being submitted as they are made of reference in related U.S. application Serial No. 10/047,749, filed October 23, 2001, pending.



Serial No. 10/706,701  
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Consideration of all the documents cited on Form PTO-1449 is requested.

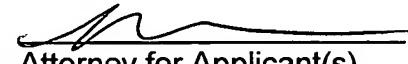
The Examiner's attention is particularly directed to

- P. Lehmann, M. Volkmann, J. Lotz, A. Baldauf, R. Roeddiger, poster presented at the AACC/CSCC, Annual Meeting, July 29 - August 2, 2001, Chicago Illinois.

The Examiner's attention is also directed to co-pending, co-owned US Serial No. 10/634,477, filed August 4, 2003 (Case Docket No. 21368), a copy of which is enclosed.

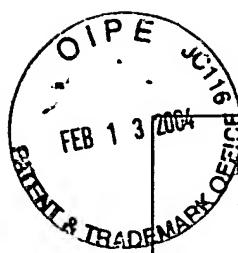
Since the Information Disclosure Statement is submitted before the mailing of the first Office Action on the merits or within three months of the filing date for the above application, no fee is due.

Respectfully submitted,

  
Attorney for Applicant(s)  
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Nutley, New Jersey 07110  
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Enclosures

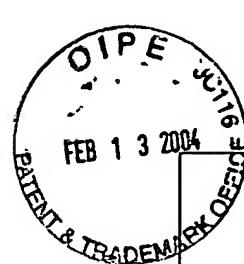
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Substitute for form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use several sheets if necessary)				<b>Complete if Known</b>			
				Application Number	10/706,701		
				Filing Date	November 12, 2003		
				First Name Inventor	Lehmann, et al.		
Sheet	1	of	3	Attorney Docket Number	21435 US		
<b>U.S. PATENT DOCUMENTS</b>							
Examiner Initials'	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited document MM-DD-YYYY		
		Number	Kind Code <sup>2</sup> (if known)				
	<b>A1</b>	4,179,337		Davis et al.	12/18/1979		
	<b>A2</b>	4,745,099		Akamatsu et al.	05/17/1988		
	<b>A3</b>	5,272,071		Chappel	12/21/1993		
	<b>A4</b>	5,324,650		Obzansky et al.	06/28/1994		
	<b>A5</b>	5,359,030		Ekwuribe	10/25/1994		
	<b>A6</b>	5,376,632		Konings et al.	12/27/1994		
	<b>A7</b>	5,541,158		Vance et al.	07/30/1996		
	<b>A8</b>	5,641,670		Treco et al.	06/24/1997		
	<b>A9</b>	5,672,662		Harris et al.	09/30/1997		
	<b>A10</b>	5,681,811		Ekwuribe	10/28/1997		
	<b>A11</b>	5,733,746		Treco et al.	03/31/1998		
	<b>A12</b>	5,733,761		Treco et al.	03/31/1998		
	<b>A13</b>	5,981,214		Skoultchi	11/09/1999		
	<b>A14</b>	5,994,127		Selden et al.	11/30/1999		
	<b>A15</b>	6,333,306		Lehmann et al.	12/25/2001		
	<b>A16</b>	6,340,742		Burg et al.	01/22/2002		
	<b>A17</b>	6,372,715		Kaltwasser et al.	04/16/2002		
	<b>A18</b>	6,528,313		Le Mouellic et al.	03/04/2003		
	<b>A19</b>	6,583,272		Bailon	06/24/2003		
	<b>A20</b>	US 2002/0160956 A1		Lehmann et al.	10/2002		
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner Initials'	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	<b>B1</b>	WO 93/09222			Transkaryotic Therapies, Inc.	05/13/1993	
	<b>B2</b>	WO 94/12650			Transkaryotic Therapies, Inc.	06/09/1994	
	<b>B3</b>	WO 95/31560			Transkaryotic Therapies, Inc.	11/23/1995	
	<b>B4</b>	WO 90/11354			Institut Pasteur	10/04/1990	
	<b>B5</b>	WO 91/06667			Cell Genesys Inc.	05/16/1991	
	<b>B6</b>	WO 91/09955			Applied Research Systems	07/11/1991	
	<b>B7</b>	WO 01/02017			F.Hoffmann-La Roche AG	01/11/2001	
	<b>B8</b>	EP 1064951			F.Hoffmann-La Roche AG	01/03/2001	
Examiner Signature					DATE CONSIDERED		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation or abstract is attached.



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			Application Number	10/706,701	
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			First Name Inventor	Lehmann, et al.	
Sheet	2	of	3	Attorney Docket Number	21435 US

### FOREIGN PATENT DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>2</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	<b>B9</b>	EP	539167		Ortho Pharmaceutical Corp.	04/28/1993	
	<b>B10</b>	EP	605963		Ortho Pharmaceutical Corp.	07/13/1994	
	<b>B11</b>	WO	93/25212		Amgen Inc.	12/23/1993	
	<b>B12</b>	WO	94/20069		Amgen Inc.	09/15/1994	
	<b>B13</b>	WO	95/11924		Enzon, Inc.	05/04/1995	
	<b>B14</b>	EP	584876		Sterling Winthrop Inc.	03/02/1994	
	<b>B15</b>	WO	92/16555		Enzon, Inc.	10/01/1992	
	<b>B16</b>	WO	94/28024		Enzon, Inc.	12/08/1994	
	<b>B17</b>	WO	97/04796		Protein Delivery, Inc.	02/13/1997	
	<b>B18</b>	WO	98/32466		Polymasc Pharmaceutical PLC	07/30/1998	
	<b>B19</b>	DE	3924705		Boehringer Mannheim GmbH	01/31/1991	
	<b>B20</b>	WO	01/87329		F.Hoffmann-La Roche AG	11/22/2001	
	<b>B21</b>	EP	640619		Amgen Inc.	03/01/1995	
	<b>B22</b>	EP	0411678		Genetics Institute Inc.	02/06/1991	
	<b>B23</b>	EP	0205564		Genetics Institute Inc.	12/30/1986	
	<b>B24</b>	EP	0286439		Ortho Pharmaceutical Corp.	10/12/1988	
	<b>B25</b>	WO	97/09996		Boehringer Mannheim GmbH	03/20/1997	
	<b>B26</b>	WO	98/41226		Boehringer Mannheim GmbH	09/24/1998	

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	<b>C1</b>	P. Lehmann, M. Volkmann, J. Lotz, A. Baldauf, R. Roeddiger, poster presented at the AACC/CSCC, Annual Meeting, July 29 - August 2, 2001, Chicago Illinois	
	<b>C2</b>	March J., Advanced Organic Chemistry, McGraw-Hill, 1977, pgs. 375-376	
	<b>C3</b>	Grasetti, D. R. & Murray, J. F., J. Appl. Biochem. Biotechnol. 119, pgs. 41-49, 1967	
	<b>C4</b>	Morpurgo M. et al., J. Bioconj. Chem. (1996) Vol. 7, pgs. 363-368	
	<b>C5</b>	Hermanson, G. T. Bioconjugate Techniques Academic Press, San Diego (1996) pgs. 147-148	
	<b>C6</b>	Annable, et al. Bull. Wld. Hlth. Org. (1972) Vol. 47 pgs. 99-112	
	<b>C7</b>	Abstract corresponding to WO 90/11354 (B4)	
	<b>C8</b>	Abstract corresponding to DE 3924705 (B19)	
Examiner Signature		DATE CONSIDERED	

<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	<b>C9</b>	Grützmacher P., et al., <i>Clinical Nephrology</i> , vol. 38, pp 92-97, 1992	
	<b>C10</b>	Wick, M.; Pinggera, W.; Lehmann, P., <i>Eisenstoffwechsel Diagnostik und Therapie der Anämien</i> , 3 <sup>rd</sup> Edition, Springer, Wien, NY, pp 5-14, 38-55, 65-80, 94-98, Sept. 1996	
	<b>C11</b>	Sunder-Plassmann G., et al., <i>Journal of the American Society of Nephrology</i> , 5, (3), pp 478 (1994).	
	<b>C12</b>	Gasche C., et al., <i>Dig. Dis. Sci.</i> , 39, (9) pp 1930-4 (1994).	
	<b>C13</b>	Sunder-Plassmann G., et al., <i>Nephrology Dialysis Transplantation</i> , 10, (11), pp 2070-2076 (1995).	
	<b>C14</b>	Mercuriali F. et al., Erythropoiesis: <i>New Dimensions in the Treatment of Anaemia</i> , 6/3, pp 67-76, (1995).	
	<b>C15</b>	Sunder-Plassmann G., et al., <i>Nephrology Dialysis Transplantation</i> , 11, (9), pp 1797-1802, (1996).	
	<b>C16</b>	Taylor J. E., et al., <i>Nephrology Dialysis Transplantation</i> , 11, (6), pp 1079-1083, (1996).	
	<b>C17</b>	Breymann, et al., <i>Eur. J. Clin. Invest.</i> , pp 123-30.	
	<b>C18</b>	Goodnough, et al., <i>Haematology</i> , 1(2), pp 163-166.	
	<b>C19</b>	MacDougall (1994) Monitoring of Iron Status & Iron Supplementation in Patients Treated with Erythropoietin. <i>Current Opinion in Nephrology &amp; Hypertension</i> 3(6) pgs. 620-625	
	<b>C20</b>	Taylor et al. (1996) Regular low-dose Intravenous Iron Therapy Improves Response to Erythropoietin in Haemodialysis Patients. <i>Nephrology, Dialysis, &amp; Transplantation</i> 11(6) pgs. 1079-1083	
	<b>C21</b>	Means, Jr. (1995) Erythropoietin in the Treatment of Anemia in Chronic Infectious, Inflammatory, & Malignant Diseases. <i>Current Opinion in Hematology</i> 2(3) pgs. 210-213	
	<b>C22</b>	Adamson (1996) Erythropoietin, Iron Metabolism, & Red Blood Cell Production. <i>Seminars In Hematology</i> 33(2) pgs. 5-9	
	<b>C23</b>	Mercuriali & Inghilleri (1995) Iron Administration to Optimize the Effect of r-HuEPO in the Surgical Setting. Erythropoiesis: <i>New Dimensions in the Treatment of Anemia</i> 6(3) pgs. 67-76	
	<b>C24</b>	Pincus et al. (August, 1990) Multicultural Study of Recombinant Human Erythropoietin in Correction of Anemia in Rheumatoid Arthritis. <i>The American Journal of Medicine</i> 89(2) pgs. 161-168.	

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